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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,399	10/30/2003	Jeffry D. Watkins	AME-08122	7480

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,399	WATKINS ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This election/restriction requirement sets forth multiple elections applicable to the Inventions of Groups I-III (see item nos. 2-4 below).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a heteromeric variable region having higher antigen binding affinity than a donor heteromeric variable region, classified in class 530, subclass 387.3.

II. Claims 13-16, drawn to a method for expressing a heteromeric variable region having higher antigen binding affinity than a donor heteromeric variable region, comprising providing a first oligonucleotide comprising an unvaried light chain framework region with altered light chain variable region CDRs and a second oligonucleotide comprising an unvaried heavy chain framework region with altered heavy chain variable region CDRs and expressing said first and second oligonucleotides to generate a heteromeric variable region binding fragment with higher antigen binding affinity than said donor heteromeric variable region, classified in class 435, subclass 326.

III. Claims 17-20, drawn to a method for expressing a heteromeric variable region having higher antigen binding affinity than a donor heteromeric variable region, comprising providing a first oligonucleotide comprising an unvaried light chain framework region and a second oligonucleotide

comprising a population of first light chain CDRs and second light chain CDRs and mixing said first oligonucleotides and said population of second oligonucleotides to generate a population of fifth oligonucleotides, comprising an unvaried light chain framework and at least one light chain donor variant and providing a third oligonucleotide comprising an unvaried heavy chain framework region and a forth oligonucleotide comprising a population of first heavy chain CDRs and second heavy chain CDRs and mixing said third oligonucleotides and said population of forth oligonucleotides to generate a population of sixth oligonucleotides, comprising an unvaried heavy chain framework and at least one heavy chain donor variant and expressing said fifth and sixth populations of oligonucleotides to produce combinations of heteromeric variable region binding fragments, classified in class 435, subclass 328.

3. This application contains claims in Groups I-III directed to the following patentably distinct species: light chain genes selected from the group:

A. A11

B. A17

C. A18

D. A19

E. A20

F. A27

G. A30

H. L1

I. L11

J. L12

K. L2

L. L5

M. L6

N. L8

O. O12

P. O2

Q. O8

The species are independent or distinct because these species are a group of genes that have different sequences and structures and, as such, would require separate searches to determine patentability for each species, so restriction as required is proper.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species in the above list from A-Q in addition to electing one of Group I-III for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no generic claims.

4. Additionally, this application contains claims in Groups I-III directed to a second patentably distinct species: heavy chain genes selected from the group:

i. VH2-5

ii. VH2-26

iii. VH2-70

iv. VH3-20

v. VH3-72

vi. VH1-46

vii. VH3-9

viii. VH3-66

ix. VH3-74

x. VH4-31

xi. VH1-18

xii. VH1-69

xiii. VH3-7

xiv. VH3-11

xv. VH3-15

xvi. VH3-21

xvii. VH3-23

xviii. VH3-30

xix. VH3-48

xx. VH4-39

xxi. VH4-59

xxii. VH5-51

The species are independent or distinct because these species are a group of genes that have different sequences and structures and, as such, would require

separate searches to determine patentability for each species, so restriction as required is proper.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species in the above list from i-xxii in addition to electing one of A-Q and one of Group I-III for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no generic claims.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consistent with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The methods of Inventions of Group II and Group III differ in the method steps and parameters, reagents used and endpoints. The invention of Group II recites a method of expressing a heteromeric variable region with higher antigen binding affinity than a donor heteromeric variable region using two oligonucleotides to express a heteromeric variable binding region fragment. The invention of Group III recites a method of expressing a heteromeric variable region with higher antigen binding affinity

than a donor heteromeric variable region using populations of oligonucleotides to express combinations of heteromeric variable binding region fragments. Thus, the inventions of Groups II and III are separate and distinct in having different method steps and parameters, reagents used and endpoints and are patentably distinct.

Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the heteromeric variable region of Group I could be made by the materially different process of Group III and vice versa. Therefore, Group I is distinct from Group II and Group III.

The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-III are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard
AU 1643